UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BAUSCH & LOMB INCORPORATED,

Plaintiff,

v.

MIMETOGEN PHARMACEUTICALS, INC.,

Defendant.

Case # 14-CV-6640-FPG

DECISION AND ORDER

MIMETOGEN PHARMACEUTICALS, INC.,

Counterclaim Plaintiff and
Third-Party Plaintiff,

v.

BAUSCH & LOMB INCORPORATED,

Counterclaim Defendant,

and

VALEANT PHARMACEUTICALS
INTERNATIONAL, INC.,

Third-Party Defendant.

INTRODUCTION

This case involves a contract between Mimetogen Pharmaceuticals, Inc. ("MPI") and Bausch & Lomb Incorporated ("B+L") regarding the development, licensing, and potential commercialization of "MIM-D3," a proprietary compound created by MPI for the treatment of dry eye syndrome. The Court is now called upon to interpret that contract and resolve the parties' competing motions for summary judgment.

BACKGROUND[1]

MPI is a privately-held biotechnology company located in Quebec, Canada. B+L is a global provider of eye care products and a wholly-owned subsidiary of third-party defendant Valeant Pharmaceuticals International, Inc. ("Valeant").

I. The Agreement

On July 17, 2013, MPI and B+L entered into a Development Collaboration and Exclusive Option Agreement (the "Agreement")[2] regarding MIM-D3, a proprietary compound created by MPI to treat dry eye syndrome. Under the Agreement, MPI granted B+L an option (the "Option") to obtain an exclusive, worldwide license to develop and commercialize products using MIM-D3. Agreement § 5.1.

The Agreement also provided for MPI to conduct an initial clinical trial, referred to as the "Initial Phase III Trial," in order to gather information about the safety and effectiveness of MIM-D3. *See id.* §§ 2, 1.28, 1.46. The protocol for the Initial Phase III Trial ("Trial Protocol") was attached as an exhibit to the Agreement. *See id.* § 1.49.

The parties' rights and obligations under the Agreement hinged on the outcome of the Initial Phase III Trial. If the Initial Phase III Trial was "Completely Successful" or "Successful," then B+L was obligated to exercise the Option at a specified price. *See id.* §§ 5.4, 5.5(a), 5.5(b). If the Initial Phase III Trial was "Partially Successful," "Inconclusive," or "Not Successful," then B+L could choose to exercise the Option, extend the Option,[3] or decide to not exercise the Option. *Id.* §§ 5.4, 5.5(c). The Agreement specifically defined each of these potential outcomes:

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[1] The following background facts are undisputed and unless otherwise noted are drawn from the following sources: the statement of undisputed facts filed by B+L and Valeant (ECF No. 47-1), the Agreement between B+L and MPI (ECF No. 41, Ex. B), the Trial Protocol attached as Exhibit B to the Agreement (ECF No. 41, Ex. C), and the Meeting Minutes issued by the FDA after a meeting on July 15, 2014 (ECF No. 41, Ex. H).

[2] The parties agree that the Agreement is valid and enforceable. ECF No. 47-1, at ¶ 7. New York law applies. Agreement § 13.11; *see* ECF No. 39.

[3] If B+L chose to extend the Option, the Agreement contemplated the possibility of one or more "Additional Trials." *See id.* §§ 1.1, 1.51, 1.55, 2, 4.8, 5.5(d)-(g).

"Completely Successful" if the results of the Initial Phase III Trial or any Additional Trial indicate that (a) the efficacy of the Licensed Product on both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, is statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that the Initial Phase III Trial or such Additional Trial is the final study required for the Approval of the Licensed Product.

"Successful" means the results of the Initial Phase III Trial or any Additional Trial indicate that (a) the efficacy of the Licensed Product on both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, is statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that there are no Significant Safety Issues and that only one additional Phase III Trial is required for Approval.

"Partially Successful" means the results of the Initial Phase III Trial or any Additional indicate that (a) the efficacy of the Licensed Product on either or both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, is not statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that there are no Significant Safety Issues and that only one additional Phase III Trial is required for Approval.

"Inconclusive" means the results of the Initial Phase III Trial or any Additional Trial are not Completely Successful, Successful, Partially Successful or Not Successful.

"Not Successful" means (a) the FDA determines, after a formal meeting and per its formal meeting minutes, that there are Significant Safety Issues, or (b) the results of the Initial Phase III Trial or any Additional Trial indicate that the efficacy of the Licensed Product on both primary sign and symptom endpoints at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, are not statistically significantly superior to the vehicle with a p value of 0.050 or less, and the FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product.[4]

Id. §§ 1.11, 1.53, 1.45, 1.25, 1.41 (emphasis added).

[4] The Agreement defines the terms "Approval" and "Licensed Product," but those terms are not at issue in this case. As it pertains to this case, "Approval of the Licensed Product" means FDA approval of MIM-D3 as a product to treat dry eye syndrome.

If the Initial Phase III Trial was Partially Successful or Inconclusive and B+L declined to either exercise or extend the Option, then B+L was obligated to pay MPI a fee of $20 million ("exit fee"). *Id.* § 5.5(c). However, if the Initial Phase III Trial was Not Successful, then B+L could walk away without making any further payments to MPI. *Id.*

II. The Initial Phase III Trial

The Initial Phase III Trial included 403 participants and was conducted over an 8-week period beginning on October 10, 2013. Participants were divided into two groups: the active drug group (which received MIM-D3) and the placebo[5] group (which received only a placebo). Both groups were placed in a Controlled Adverse Environment chamber ("CAE chamber"), which subjected the participants' eyes to a stressful, drying environment.

After exposing participants to the CAE chamber, researchers evaluated the effectiveness of MIM-D3 by measuring certain signs and symptoms and then comparing the active drug group to the placebo group. The Trial Protocol separated the signs and symptoms into three categories: Primary Efficacy Variables,[6] Secondary Efficacy Variables, and Exploratory Efficacy Variables. *See* Trial Protocol § 6.1.

In May 2014, MPI provided B+L with the results of the Initial Phase III Trial. The parties agree that the Initial Phase III Trial was not Completely Successful, Successful, or Partially Successful as those terms are defined in the Agreement. Because the Agreement does not independently define the term Inconclusive, the parties' rights and obligations under the Agreement depend on whether the Initial Phase III Trial was Not Successful.

The parties agree that part (a) of the Not Successful definition does not apply because the FDA did not determine that there were any Significant Safety Issues in the Initial Phase III Trial.

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[5] The Agreement and the Trial Protocol both refer to the placebo as the "vehicle." *See* Trial Protocol § 7.1.2.

[6] The Trial Protocol also describes the Primary Efficacy Variables as "primary endpoints" and "endpoints." *See* Trial Protocol §§ 6.1.1, 6.1.4. See below for a more detailed discussion regarding the word "endpoint."

The parties also agree that the first half of part (b) does apply because the results of the Initial Phase III Trial did not indicate that MIM-D3 performed "statistically significantly superior" to the placebo with respect to the primary sign and symptom endpoints. The parties' dispute focuses on the second half of part (b),[7] which consists of the following language:

> [T]he FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product.

Agreement § 1.41(b)(2). If that language applies, then the Initial Phase III Trial was Not Successful; if it does not, then the Initial Phase III Trial was Inconclusive.

III. FDA Meeting Minutes

On July 15, 2014, representatives from MPI and B+L met with FDA officials to review and discuss the Initial Phase III Trial results. The FDA then circulated the formal "Meeting Minutes" from that meeting. The Meeting Minutes include questions submitted by MPI, the FDA's responses to those questions, and a summary of any discussion that took place at the meeting regarding those questions.

The first question posed to the FDA was: "Does the Agency agree that the assessed endpoints can be used as a primary sign endpoint in support of the approval of the product?" *See* Meeting Minutes at 2. With respect to the change in participants' "corneal fluorescein staining in the central region" following exposure to the CAE chamber, the FDA responded as follows:

> A change in corneal fluorescein staining in a pre-specified area (e.g., central region) at a pre-specified time following exposure to a dry environment is acceptable as a "sign endpoint" when coupled with a "symptom endpoint" to support the efficacy of a product for the treatment of dry eyes. The use of proprietary testing procedures may raise questions about the ability to generalize the test results to support a more generalized label.

[7] Although the Agreement does not separate part (b) into different sub-parts, for ease of reference the Court will use "1.41(b)(2)" to refer to the second half of part (b) of section 1.41.

Id. With respect to the change in participants' "fluorescein staining in the total cornea (sum of the inferior, central and superior regions)" following exposure to the CAE chamber, the FDA provided the same response. *Id.* at 2-3. Fluorescein staining in the central region of the cornea and fluorescein staining in the total cornea[8] were both measured as Exploratory Efficacy Variables in the Initial Phase III Trial. *See* Trial Protocol § 6.1.3; ECF No. 47-1, at ¶ 29.

Second, MPI asked: "Does the Agency agree that the assessed endpoints can be used as a primary symptom endpoint in support of the approval of the product?" Meeting Minutes at 3. With respect to participants' response to a question about "blurred vision" in the OSDI Questionnaire,[9] the FDA provided the following response:

> It is not recommended. A change in a patient's response to a question about an ocular symptom at a pre-specified time is acceptable as a "symptom endpoint" when coupled with a "sign endpoint" to support the efficacy of a product for the treatment of dry eyes. For the purposes of assessing vision, it is generally expected that vision would be measured using a standardized chart. A single question concerning the quality of an individual's vision may be acceptable as a "symptom endpoint." We are not aware of validation studies of any single (or subset) question from the OSDI Questionnaire. The use of proprietary testing procedures may raise questions about the ability to generalize the test results to support a more generalized label.

Id. The FDA also applied this response to all other symptom endpoints listed by MPI. *Id.*

MPI's third question read as follows:

> If the following sign and symptom endpoints, specifically, change from Pre-CAE_{SM} to Post-CAE_{SM} in fluorescein staining in the central region or total cornea (sum of the inferior, central and superior regions) and one of the following OSDI questions "blurred vision" or "poor vision" that demonstrated improvements in the recently completed Phase 3 study (MIM-725) are replicated as primary endpoints in a subsequent Phase 3 study, would the clinical data from these two Phase 3 studies and the Phase 2 study (MIM-724) be sufficient evidence to support efficacy of a dry eye indication? Would an additional efficacy study be required?

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[8] For the sake of simplicity, the Court will refer to these two variables as "central cornea staining" and "total cornea staining."

[9] OSDI stands for "Ocular Surface Disease Index." *See* ECF No. 47-1, at ¶ 30. Participants' answers to questions in the OSDI Questionnaire were measured as Exploratory Efficacy Variables in the Initial Phase III Trial. *See* Trial Protocol § 6.1.3.

Id. at 4. The FDA gave the following response:

> A single efficacy study is unlikely to be sufficient to support a New Drug Application (NDA) because after an adjustment for multiplicity, it appears that neither of the completed studies demonstrated efficacy of the proposed drug product. It is recommended that at least two additional efficacy studies be conducted.

Id.

IV. B+L's Decision to Not Exercise the Option

On August 1, 2014, MPI sent the Meeting Minutes to B+L. B+L's receipt of the Meeting Minutes triggered a 30-day deadline for B+L to decide how to proceed with respect to exercising, extending, or deciding not to exercise the Option. *See* Agreement § 5.4. Ultimately, B+L allowed the 30-day deadline to come and go without exercising or extending the Option. B+L did not pay MPI the exit fee.

V. Procedural History

B+L initiated this action by seeking a declaratory judgment that B+L is not obligated to make any further payments to MPI under the Agreement. ECF No. 1. MPI, in turn, asserted various counterclaims against B+L and Valeant. ECF No. 6.

MPI now moves for partial summary judgment on its breach of contract claim against B+L. ECF No. 41. MPI argues that the Initial Phase III Trial was Inconclusive and that B+L breached section 5.5(c) of the Agreement by failing to pay the exit fee when it declined to exercise or extend the Option. *Id.*

B+L and Valeant cross-move for summary judgment. ECF No. 47.[10] According to them, the Initial Phase III Trial was Not Successful and no payment was due to MPI. B+L seeks judgment on its complaint and Valeant seeks dismissal of MPI's third-party claim. *Id.*[11]

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[10] B+L and Valeant have also moved to strike certain exhibits submitted by MPI. ECF No. 47-2, at 21-23. The Court does not rely on any of the challenged exhibits in this decision. Therefore, the motion to strike is MOOT.

[11] For the sake of simplicity, the Court will occasionally refer to B+L and Valeant together as "B+L."

LEGAL STANDARD

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). On the other hand, the non-moving party may defeat a summary judgment motion by producing sufficient specific facts to establish that there is a genuine issue of material fact for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

When reviewing a motion for summary judgment, the court must resolve genuinely disputed facts in favor of the non-moving party and must view inferences to be drawn from the facts in the light most favorable to the non-moving party. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 158-59 (1970). However, a party may not "rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment." *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 12 (2d Cir. 1986).

DISCUSSION

As detailed above, the parties' dispute regarding their rights and obligations under the Agreement turns on the following language, which is contained in the Agreement's definition of the term Not Successful:

> [T]he FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product.

Agreement § 1.41(b)(2). If that language applies, then the Initial Phase III Trial was Not Successful and B+L had the right to walk away without making any further payments to MPI. *See id.* § 5.5(c). If it does not, then the Initial Phase III Trial was Inconclusive and B+L breached the Agreement by failing to pay the exit fee. *Id.*

The Court will begin with a discussion of the relevant legal principles and then proceed to an analysis of the parties' competing interpretations. For the reasons that follow, the Court

finds that section 1.41(b)(2) is unambiguous and does not apply to the Initial Phase III Trial. Accordingly, the motion for summary judgment by B+L and Valeant is DENIED and the motion for partial summary judgment by MPI is GRANTED.

I. Relevant Principles of Contract Interpretation

"The primary objective of a court in interpreting a contract is to give effect to the intent of the parties as revealed by the language of their agreement." *Compagnie Financiere de CIC et de L'Union Europeenne v. Merrill Lynch, Pierce, Fenner & Smith Inc.*, 232 F.3d 153, 157 (2d Cir. 2000) (Sotomayor, J.); *see also MHR Capital Partners LP v. Presstek, Inc.*, 12 N.Y.3d 640, 645 (2009) ("It is well settled that a contract is to be construed in accordance with the parties' intent, which is generally discerned from the four corners of the document itself."). In construing a contract, a court should "read the contract as a whole" and "avoid any interpretation that would render a contractual provision without force and effect." *Luitpold Pharm., Inc. v. Ed. Geistlich Sohne A.G. Fur Chemische Industrie*, 784 F.3d 78, 87 (2d Cir. 2015) (citing *Westmoreland Coal Co. v. Entech, Inc.*, 100 N.Y.2d 352, 358 (2003) and *Two Guys from Harrison-N.Y., Inc. v. S.F.R. Realty Assocs.*, 63 N.Y.2d 396, 403 (1984)).

In a contract dispute, summary judgment is generally appropriate only if the contract is unambiguous. *Compagnie*, 232 F.3d at 157. "Contract language is ambiguous if it is capable of more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement." *Id.* at 158 (quoting *Sayers v. Rochester Tel. Corp. Supplemental Mgmt. Pension Plan*, 7 F.3d 1091, 1095 (2d Cir. 1993)) (internal quotations omitted); *see also Greenfield v. Philles Records, Inc.*, 98 N.Y.2d 562, 569 (2002) ("A contract is unambiguous if the language it uses has a definite and precise meaning, unattended by danger of misconception in the purport of the agreement itself, and concerning which there is no reasonable basis for a difference of opinion.") (internal quotations and

alterations omitted). Simply put, "[a] contract is ambiguous when reasonable minds could differ as to its meaning." *Luitpold*, 784 F.3d at 87 (quoting *Van Wagner Advert. Corp. v. S & M Enterprises*, 67 N.Y.2d 186, 191 (1986)).

Language in a contract "is not rendered ambiguous just because one of the parties attaches a different, subjective meaning to one of its terms." *Moore v. Kopel*, 237 A.D.2d 124, 125 (1st Dep't 1997); *accord Law Debenture Trust Co. of N.Y. v. Maverick Tube Corp.*, 595 F.3d 458, 467 (2d Cir. 2010) (quoting *Hunt Ltd. v. Lifschultz Fast Freight, Inc.*, 889 F.2d 1274, 1277 (2d Cir. 1989)). As the Second Circuit has stressed, "it is the rare sentence that cannot be read in more than one way if the reader is willing either to suspend the rules of common English usage or ignore the conventions of a given commercial setting. . . . Contorted semanticism must not be permitted to create an issue where none exists." *Wards Co. v. Stamford Ridgeway Assocs.*, 761 F.2d 117, 120 (2d Cir. 1985); *see also Hunt*, 889 F.2d at 1277 ("The court is not required to find the language ambiguous where the interpretation urged by one party would strain the contract language beyond its reasonable and ordinary meaning.") (quoting *Bethlehem Steel Co. v. Turner Const. Co.*, 2 N.Y.2d 456, 459 (1957)) (internal quotations and alterations omitted).

Under New York law,[12] the question of ambiguity must be determined "from the face of the agreement, without reference to extrinsic evidence." *Collins v. Harrison-Bode*, 303 F.3d 429, 433 (2d Cir. 2002) (citing *Kass v. Kass*, 91 N.Y.2d 554, 566 (1998)). At the same time, courts consider the words in a contract "not as if isolated from the context, but in the light of the obligation as a whole and the intention of the parties as manifested thereby. Form should not prevail over substance and a sensible meaning of words should be sought." *Kass*, 91 N.Y.2d at 566 (quoting *William C. Atwater & Co., Inc. v. Panama R. Co.*, 246 N.Y. 519, 524 (1927)).

[12] *See* above note 2.

Whether a given contract is ambiguous is a question of law for the court to decide. *Luitpold*, 784 F.3d at 88; *Kass*, 91 N.Y.2d at 566.

II. MPI's Interpretation of Section 1.41(b)(2)

MPI's interpretation of section 1.41(b)(2) focuses on the words "sign" and "symptom." MPI argues that those words refer to the *variables* that were measured at the Initial Phase III Trial, not the *data* or *results* of that trial. Thus, as long as the FDA agreed that one of the variables measured in the Initial Phase III Trial could be used as the primary variable in an application for FDA approval, then section 1.41(b)(2) would not apply—even if that variable would have to be measured in a subsequent study and even if no data from the Initial Phase III Trial could be used to show the effectiveness of MIM-D3.

This interpretation is consistent with the plain meaning of the words "sign" and "symptom." Although neither of those words is defined in the Agreement, the parties do not dispute their meanings. A sign is an *objective* indication of disease, whereas a symptom is a *subjective* indication of disease. *See* ECF No. 47-2, at 2 n. 4-5 (quoting Dorland's Medical Dictionary for Health Consumers (2007)); Stedman's Medical Dictionary at 1766, 1884 (28th ed. 2006), *available at* Westlaw STEDMANS 818000, 874230. For example, a doctor might determine whether her patient has pneumonia by measuring common signs (inflammation in the lungs) and symptoms (fatigue, difficulty breathing) of that disease. In the context of a clinical trial, signs and symptoms are simply *the things that get measured*.[13] By contrast, words like "data" and "results" refer to *the measurement of those things*.

MPI's interpretation is also consistent with basic English grammar. There is no doubt that the subject of section 1.41(b)(2) is "the FDA"; the FDA is the entity whose action (to agree or "not agree") determines whether section 1.41(b)(2) applies. The parties' dispute is about the

[13] In their cross-motion for summary judgment, B+L and Valeant agree that signs and symptoms "are merely the categories of measurement." ECF No. 47-2, at 14.

predicate of section 1.41(b)(2), *i.e.*, to what must the FDA "not agree"? Because the words "that either a sign or symptom" immediately follow the word "agree," the natural implication is that the FDA's action is directed at "either a sign or a symptom." In other words, "either a sign or a symptom" is the *object* of section 1.41(b)(2).[14] This is the most logical reading of section 1.41(b)(2) and justifies MPI's focus on the words "sign" and "symptom."

The repetition of "sign" and "symptom" near the end of section 1.41(b)(2) further justifies MPI's focus on those words. If the FDA agrees that "a sign or a symptom . . . can be used *as the primary sign or symptom* . . .," then section 1.41(b)(2) does not apply. The word "as" is a preposition in this context, meaning that the phrase "primary sign or symptom" refers to the *role* or *function* that "either a sign or a symptom, that were assessed. . ." must be able to fulfill. Because the words "sign" and "symptom" simply refer to the variables that are measured in a clinical trial, rather than the data or results of that trial, this common sense reading of the phrase "as the primary sign or symptom" further supports MPI's interpretation.

Moreover, MPI's interpretation gives a common sense purpose to each clause and phrase in section 1.41(b)(2). The most sensible reading of the clause "that were assessed in the Initial Phase III Trial or the Additional Trial," which immediately follows "either a sign or a symptom" and is separated from the rest of section 1.41(b)(2) by commas, is that it is an *adjective clause*; in other words, it describes the *type* of signs and symptoms about which the FDA must "not agree." Next, the phrase "can be used as the primary sign or symptom to support the Approval of the Licensed Product" is the *substance* of what the FDA must "not agree" to. "[A]s the primary sign or symptom" refers to the *role* that the specific sign or symptom must be able to play, and "to support the Approval of the Licensed Product" refers to the *objective* for which the sign or

[14] English sentences generally follow a subject-verb-object sentence structure. *See, e.g.*, M. H. Sam Jacobson, A Checklist for Drafting Good Contracts, 5 J. Ass'n Legal Writing Directors 79, 105 (2008) ("Sentences written in a simple structure (subject-verb-object) are easy to read and understand."); Peter M. Tiersma, Communicating with Juries: How to Draft More Understandable Instructions, 10 Scribes J. Legal Writing 1, 19 (2006) ("Most sentences in English have what linguists call an 'SVO' word order: subject-verb-object.").

symptom must be able to be used. This reading gives a common sense purpose to each part of section 1.41(b)(2) by recognizing that the words "that were assessed . . ." and "can be used . . ." serve distinct purposes: section 1.41(b)(2) does not apply if (1) X is a sign or symptom that was assessed at the Initial Phase III Trial and (2) the FDA agrees that X can be used as the primary sign or symptom to support Approval of the Licensed Product.

Lastly, MPI's interpretation of section 1.41(b)(2) is bolstered by reading that section in context with the Agreement as a whole. The Agreement's definitions of "Completely Successful," "Successful," "Partially Successful," and "Not Successful"[15] mirror each other in several important respects. Each definition includes language regarding whether the "efficacy" of MIM-D3 on "primary sign and symptom endpoints" was "statistically significantly superior to the vehicle with a p value of 0.050 or less." *See* Agreement §§ 1.11(a), 1.53(a), 1.45(a), 1.41(b)(1). The definitions for Completely Successful, Successful, and Partially Successful each include specific language regarding how many additional Phase III Trials would be required to secure FDA Approval. *See id.* §§ 1.11(b) (no additional trials required), 1.53(b) (only one additional trial required), 1.45(b) (only one additional trial required). The definitions for Successful, Partially Successful, and Not Successful each employ parallel language to address the possibility that there are Significant Safety Issues with MIM-D3. *See id.* §§ 1.53(b), 1.45(b), 1.41(a). But section 1.41(b)(2) is completely unique. That language does not appear in the definitions for any of the other possible outcomes. In fact, the language in section 1.41(b)(2) is the *only* language in *any* of these definitions that is not repeated elsewhere. This strongly suggests that section 1.41(b)(2) is meant to address a categorically different aspect of the Initial Phase III Trial—namely, whether any of the variables measured at that trial could be used as the primary variable in an application for FDA approval.

[15] The Agreement does not independently define the term "Inconclusive." *See* Agreement § 1.25.

B+L advances four arguments in opposition to MPI's interpretation, none of which are persuasive. First, B+L argues that MPI's interpretation "would require the Court to change the language of the contract and read numerous new words into the definition of Not Successful." ECF No. 47-2, at 15-16. Specifically, B+L argues that MPI interprets section 1.41(b)(2) to read as follows:

> [T]he FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial . . ., can be used as the primary sign or symptom *endpoint in an Additional Trial*.

Id. (emphasis in original).

This argument mischaracterizes MPI's interpretation. MPI believes that the Initial Phase III Trial could fall outside the purview of section 1.41(b)(2) *even if* an additional trial would be required to demonstrate the effectiveness of MIM-D3, not *only if* an additional trial would be required. Of course, one sensible way a sign or symptom can be used "to support the Approval of the Licensed Product" is for that sign or symptom to be measured at an additional trial. But that is true regardless of whether the words "in an Additional Trial" appear in section 1.41(b)(2). MPI's interpretation does not require those words to be added into the Agreement.

Similarly, although adding the word "endpoint" to section 1.41(b)(2) would be consistent with MPI's interpretation, the interpretation in no way depends on such an addition. The word endpoint is used elsewhere in the Agreement but never defined. According to B+L, endpoints are "direct and measurable characteristics of treatment outcome" and can be primary or secondary efficacy variables—but not exploratory efficacy variables. ECF No. 47-2, at 6. Primary variables are the most important because "the only thing the FDA considers approvable are the primary endpoints for that study." *Id.* MPI defines endpoint as "a variable linked to the efficacy (e.g., prolongation of survival) or safety issue of the trial." ECF No. 41-2, at 17 (citing Segen's Medical Dictionary (2012)). The FDA has provided the following definition: "The

measurement that will be statistically compared among treatment groups to assess the effect of treatment and that corresponds with the clinical trial's objectives, design, and data analysis." U.S. Food & Drug Admin., Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (2009), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282. The Trial Protocol for the Initial Phase III Trial describes the Primary Efficacy Variables as "primary endpoints" and "endpoints," *see* Trial Protocol §§ 6.1.1, 6.1.4, suggesting that the terms "primary variable," "primary endpoint," and "endpoint" are synonymous.

The subtle differences between these definitions are insignificant. To put it simply, an endpoint is the predetermined goal of a clinical trial. Naturally, the goal of a trial is expressed in terms of a variable that is being measured at that trial. According to B+L's own definition and the Trial Protocol, the word endpoint is used to refer to primary efficacy variables. Because section 1.41(b)(2) includes the word "primary," adding the word "endpoint" would not change the meaning of section 1.41(b)(2) at all—much less add meaning that is helpful to MPI's interpretation.

Second, B+L argues that "it would be illogical to accept that 'used to support Approval' means the same thing as 'used in an Additional Trial to support Approval'" because "[c]linical trials do not support Approval; the trial must be successful and result in an assessed sign or symptom that is sufficiently significant to support regulatory Approval." ECF No. 47-2, at 16.

Again, B+L mischaracterizes MPI's interpretation. MPI does not dispute that statistically significant data is necessary for FDA approval. Rather, MPI's position is that measuring acceptable primary variables is *also* a necessary condition for FDA approval. Indeed, B+L agrees that "[t]he Primary Efficacy Variables in a clinical trial are the most important because 'the only thing the FDA considers approvable are the primary endpoints for that study.'" ECF

No. 47-2, at 6 (quoting ECF No. 47-10, Tonetta Dep. at 69:16-21). MPI's common sense interpretation is that if the FDA agrees that a secondary or exploratory variable measured at the Initial Phase III Trial would be acceptable as a primary variable, then section 1.41(b)(2) does not apply—even if that variable would have to be measured at an additional trial. This interpretation does not require MPI to argue that an application for FDA approval could somehow succeed without significant data.

Third, B+L argues that MPI's interpretation would "nullify" section 1.41(b). Before the Agreement was signed in July 2013, MPI conducted a "Phase II Trial" regarding MIM-D3. ECF No. 47-3, Ex. B, Attachment 1 ("Synopsis of the Phase 2 Study MIM-724"). Total cornea staining was a "Primary Efficacy Measure" at the Phase II Trial and staining in the particular regions of the cornea were "Secondary Efficacy Measures." *Id.* On December 6, 2011, at the conclusion of the Phase II Trial, representatives from MPI spoke with the FDA via teleconference about the Phase II Trial data and MPI's proposed design for future studies. ECF No. 47-3, Ex. C ("Phase II Meeting Minutes"). The FDA tentatively agreed that cornea staining in the *inferior region* was acceptable as a "sign primary efficacy endpoint" for a future Phase III study. Phase II Meeting Minutes at 5. Given that history, B+L contends that there was "very minimal risk" that the FDA would decide after the Initial Phase III Trial that total cornea staining or central cornea staining were not acceptable as primary sign endpoints. ECF No. 47-3, at ¶ 28. B+L argues that "[i]t would be illogical to conclude that B+L agreed to pay MPI $20 million if the FDA merely conformed to its well-established existing practice by approving as a primary sign in an Additional Trial a measurement that had been used in a previous clinical trial." *Id.* at ¶ 30.

B+L's argument is unavailing. Even assuming B+L is correct that there was "very minimal risk" the FDA would find that total cornea staining or central cornea staining were not

acceptable as primary sign endpoints, that does not "nullify" section 1.41(b) or lead to an absurd result.[16] It simply means that, at the time the parties entered into the Agreement, the chances were low that the Initial Phase III Trial would be Not Successful based on section 1.41(b).[17] The Court's role is not to reach back in time, weigh the different permutations of trial outcomes against the prices associated with those outcomes, and then make sure that the Agreement would have been a "good deal" to both parties at the time it was executed. The Court's role is to "give effect to the intent of the parties *as revealed by the language of their agreement*." *Compagnie*, 232 F.3d at 157 (emphasis added). "The best evidence of what parties to a written agreement intend is what they say in their writing." *Postlewaite v. McGraw-Hill, Inc.*, 411 F.3d 63, 69 (2d Cir. 2005) (quoting *Greenfield v. Philles Records, Inc.*, 98 N.Y.2d 562, 569 (2002)). There is no doubt that the language in the Agreement was drafted by sophisticated business parties and negotiated at arm's length. MPI's interpretation of section 1.41(b)(2) would not nullify any part of that Agreement or lead to an absurd result but would simply reveal the intent of the parties through a natural and common sense reading of the language they agreed upon.

Fourth, B+L argues that MPI's interpretation "ignores the import of the words 'that were assessed,' which signifies that the parties intended to refer to not just the thing that is being measured (the sign or symptom) but rather to the assessment – the data or results." ECF No. 47-2, at 17.

B+L's fourth argument, like the previous three, fails to diminish MPI's interpretation in any way. MPI does not ignore the import of the words "that were assessed." To the contrary, as

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[16] B+L argues that, under MPI's interpretation, it would be "bound" to pay for numerous unsuccessful trials so long as MPI chose appropriate variables for those trials. ECF No. 55. But this ignores the fact that the fee referred to in section 5.5(c) of the Agreement is an *exit* fee—it clearly allowed B+L to exit the Agreement after one Inconclusive trial if it decided that the data was unsatisfactory.

[17] Of course, the Initial Phase III Trial could have also been Not Successful if the FDA found that there were Significant Safety Issues. *See* Agreement § 1.41(a). B+L does not provide any argument regarding the likelihood of that scenario, which undermines its premise that MPI's interpretation would leave "virtually no situation where a clinical trial of MIM-D3 could ever be Not Successful." ECF No. 47-2, at 16.

described above, MPI gives those words their most natural meaning and purpose: the clause "that were assessed in the Initial Phase III Trial or the Additional Trial," which immediately follows "either a sign or a symptom" and is separated from the rest of section 1.41(b)(2) by commas, is an *adjective clause*; it modifies the object of the sentence ("either a sign or a symptom") and describes the type of variables about which the FDA must "not agree." B+L would change that clause to the *object* of the sentence, to the thing that the FDA's action is directed towards. For the reasons described above, it is clear that "either a sign or a symptom" is the object of the FDA's action. The defects of B+L's own interpretation are discussed in more detail below, but for now it suffices to say that MPI gives a reasonable meaning to the words "that were assessed."

To summarize: MPI has put forth a common sense, reasonable interpretation of section 1.41(b)(2). MPI's interpretation gives each word its natural and ordinary meaning, gives each phrase and clause its logical purpose, and makes sense in context with how the other trial outcomes are defined in the Agreement. Therefore, the cross-motion for summary judgment filed by B+L and Valeant (ECF No. 47) is DENIED.

III. B+L's Interpretation of Section 1.41(b)(2)

MPI's common sense interpretation of section 1.41(b)(2) does not end the Court's inquiry. MPI has also moved for summary judgment, arguing that section 1.41(b)(2) is unambiguous and asking the Court to find that B+L breached the Agreement as a matter of law. *See* ECF No. 41. If reasonable minds could differ as to the meaning of section 1.41(b)(2), then summary judgment would not be warranted. *See, e.g.*, *Seiden Assocs., Inc. v. ANC Holdings, Inc.*, 959 F.2d 425, 428 (2d Cir. 1992). Therefore, the Court now turns to B+L's interpretation of section 1.41(b)(2). The Court finds that it is untenable.

B+L's logic begins with the fact that an application for FDA approval of a product must demonstrate substantial evidence of that product's effectiveness, derived from adequate and

well-controlled clinical investigations. ECF No. 47-2, at 12 (citing 21 U.S.C. § 355(d)). To prove effectiveness, the FDA ordinarily requires at least two adequate and well-controlled studies, each of which must show that the product had "a statistically significant effect on a clinically meaningful endpoint." *Id.* (citing ECF No. 47-3, Ex. A, at 11).[18]

In light of those regulatory requirements, B+L reads section 1.41(b)(2) to apply unless the FDA agreed "that the results of the assessed sign or symptom (i.e., data) could be used to demonstrate the requisite efficacy needed for regulatory approval." *Id.* In other words, B+L's position is that "the FDA had to agree in the meeting that a sign or symptom that was assessed in the Initial Phase III Trial had demonstrated a statistically significant effect such that it can be used as one of the 'at least two' studies of a primary sign or symptom that will support substantial evidence of effectiveness." *Id.* at 13. Because the FDA did not agree that any data from the Initial Phase III Trial could be used to show the effectiveness of MIM-D3, B+L argues that section 1.41(b)(2) applies and the Initial Phase III Trial was Not Successful.

B+L's interpretation fails for several basic reasons. First, B+L's interpretation would require the Court to suspend the rules of common English usage and add words into the Agreement. Section 1.41(b)(2) does not contain the words "data," "results," or "efficacy." B+L attempts to read in those concepts by pointing to the words "either a sign or a symptom, that were assessed. . ." ECF No. 47-2, at 13-14 (arguing that "'data' is synonymous with 'sign or symptom[] that were assessed.'") (alteration in original). But as described above, the words "sign" and "symptom" simply refer to the variables themselves, not the data collected by measuring those variables. In their cross-motion for summary judgment, B+L and Valeant agree that signs and symptoms "are merely the categories of measurement." ECF No. 47-2, at 14.

[18] The Court accepts information regarding the FDA's approval process as relevant to the context in which B+L and MPI entered into the Agreement. *See Thompson v. Gjivoje*, 896 F.2d 716, 721 (2d Cir. 1990) (stating that courts interpreting contract language should give "due consideration to the surrounding circumstances and apparent purpose which the parties sought to accomplish") (quoting *William C. Atwater & Co. v. Panama R.R. Co.*, 246 N.Y. 519, 524 (1927) (internal quotations omitted). Therefore, MPI's motion to strike (ECF No. 54) is DENIED.

By pointing to the word "assessed," B+L ignores the important difference between "either a sign or a symptom, that were assessed . . ." and "the assessment of a sign or symptom that . . ." In the first scenario—which, of course, is what actually appears in section 1.41(b)(2)—the words "sign" and "symptom" are given prominence and are used as the object of the FDA's action. The words "that were assessed . . .," which are separated from the rest of the sentence by commas, simply describe the type of sign or symptom that the FDA must agree about. In the second scenario, which is what B+L reads the contract to say, the focus has been completely changed: the word "assessment" would now be the object of the FDA's action.

B+L also points to the word "support" and argues that only data can "support the Approval of the Licensed Product." ECF No. 47-2, at 14. But this argument is refuted by B+L's own characterization of the FDA approval process. According to B+L, the FDA requires an applicant to prove effectiveness through at least two adequate and well-controlled studies, each of which must show that the product had "a statistically significant effect *on a clinically meaningful endpoint*." *Id.* at 12 (citing ECF No. 47-3, Ex. A, at 11) (emphasis added). In other words, while statistically significant data is obviously important and necessary, measuring acceptable variables is *also* necessary for FDA approval. B+L does not deny that fact.[19]

Thus, B+L cannot point to any words in section 1.41(b)(2) that reasonably implicate the concept of data or efficacy. B+L's interpretation would require the Court to re-write section 1.41(b)(2) by adding in words and changing the focus of the sentence.

Second, if the parties had wanted section 1.41(b)(2) to mean what B+L argues it does, they could have easily said so. The parties could have agreed on the following language: "the FDA does not agree that any data from the Initial Phase III Trial or Additional Trial can be used

[19] Indeed, the Meeting Minutes following the Initial Phase III Trial demonstrate the importance of measuring acceptable variables. In response to Question 2 regarding whether the OSDI questionnaire could be used "as a primary symptom endpoint in support of the approval of the product," the FDA said "[i]t is not recommended." *See* Meeting Minutes at 3. Thus, even if MPI provided data showing that MIM-D3 had a statistically significant effect on patients' answers to the OSDI questionnaire, it would likely not "support" approval.

to demonstrate the efficacy of the Licensed Product." But instead, they agreed that Not Successful meant "[t]he FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product." The existence of an obvious, simple, and straightforward way to convey the meaning that B+L ascribes to section 1.41(b)(2) belies its interpretation. In contrast, there is no obvious alternative way to convey the meaning that MPI ascribes to section 1.41(b)(2).

Third, reading section 1.41(b)(2) in context with the entire Agreement discredits B+L's interpretation. B+L asserts that section 1.41(b)(2) applies unless the Initial Phase III Trial can be used as one of the "at least two" studies required for FDA approval. But elsewhere in the Agreement, the parties used completely different language to specifically address the issue of how many additional trials would be required for FDA approval. For a trial to be Completely Successful, the FDA must agree that the trial "is the final study required for the Approval of the Licensed Product." Agreement § 1.11(b). For a trial to be Successful or Not Successful, the FDA must agree that "only one additional Phase III Trial is required for Approval." *Id.* §§ 1.53(b), 1.45(b).

If the parties had intended the definition of Not Successful to address whether the trial at issue could be used as one of the "at least two" studies required for FDA approval, they would have employed the same language they did in other parts of the Agreement.[20] *See Int'l Fid. Ins. Co. v. Cty. of Rockland*, 98 F. Supp. 2d 400, 412 (S.D.N.Y. 2000) ("Sophisticated lawyers . . . must be presumed to know how to use parallel construction and identical wording to impart identical meaning when they intend to do so, and how to use different words and construction to

[20] For example, the parties could have agreed to the following language: "the FDA does not agree that only one additional Phase III Trial is required for Approval." The parties also could have used words such as "data" or "results"—each of which appears numerous times throughout the Agreement, but not in section 1.41(b)(2).

establish distinctions in meaning."); *Bank of N.Y. Mellon Trust Co. v. Morgan Stanley Mortg. Capital, Inc.*, 821 F.3d 297, 306–07 (2d Cir. 2016) (citing *Int'l Fid. Ins. Co.*); *Nat'l Basketball Ass'n v. Nat'l Basketball Players Ass'n*, No. 04-CV-9528, 2005 WL 22869, at *8 (S.D.N.Y. Jan. 3, 2005).

Indeed, even the use of similar but not identical language in a contract implies that the parties intended different meanings. *See, e.g., Eastman Kodak Co. v. Altek Corp.*, 936 F. Supp. 2d 342, 355 (S.D.N.Y. 2013) ("The use of similar but different terms in a single contract strongly implies that the terms are to be accorded different meanings.") (quoting *NFL Enters. LLC v. Comcast Cable Commc'ns*, LLC, 51 A.D.3d 52 (1st Dep't 2008)); *Gov't Employees Ins. Co. v. Saco*, No. 12-CV-5633, 2015 WL 1527611, at *4 (E.D.N.Y. Mar. 31, 2015) ("New York case law has developed a general principle that where a contract uses similar, but not identical, language in different provisions, the use of different terms implies that the terms are to be accorded different meanings."). This case presents a much simpler scenario: the language in section 1.41(b)(2) is *completely different* from the language in the definitions for other outcomes. The only reasonable inference is that the parties intended section 1.41(b)(2) to address a completely different aspect of the Initial Phase III Trial.

In sum, there is no support for including concepts such as data or efficacy in section 1.41(b)(2). B+L's interpretation would "strain the contract language beyond its reasonable and ordinary meaning," *Hunt*, 889 F.2d at 1277, and would amount to "[c]ontorted semanticism," *Wards*, 761 F.2d at 120. B+L essentially asks the Court to rewrite section 1.41(b)(2) by adding in new words, changing the entire focus of the sentence, and ignoring the language used elsewhere in the Agreement. When viewed objectively by a reasonably intelligent person who

has examined the context of the entire Agreement, MPI's interpretation of section 1.41(b)(2) is the only reasonable one. Therefore, the Court finds that section 1.41(b)(2) is unambiguous.[21]

IV. Breach of Contract

To recover on a breach of contract claim under New York law, a plaintiff must prove by a preponderance of the evidence (1) the existence of a valid contract; (2) adequate performance by the plaintiff; (3) breach by the defendant; and (4) damages caused by that breach. *See, e.g.*, *Diesel Props S.r.l. v. Greystone Bus. Credit II LLC*, 631 F.3d 42, 52 (2d Cir. 2011). Only the third element is at issue here.[22]

Having found that section 1.41(b)(2) is unambiguous, the Court now turns to the final point of contention between the parties: whether the FDA in fact agreed that "either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product." If it did, then the Initial Phase III Trial was Inconclusive and B+L breached the Agreement by failing to pay the exit fee when it chose not to exercise or extend the Option. *See* Agreement § 5.5(c).

MPI relies on the FDA's answer to Question 1 in the Meeting Minutes. Question 1 reads as follows: "Does the Agency agree that the assessed endpoints can be used as a primary sign endpoint in support of the approval of the product?" *See* Meeting Minutes at 2. MPI asked this question with respect to central cornea staining and total cornea staining, both of which are signs and both of which were measured as Exploratory Efficacy Variables in the Initial Phase III Trial. *See id.*; Trial Protocol § 6.1.3; ECF No. 47-1, at ¶ 29. The FDA provided the same response for both signs:

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[21] Because the Agreement is unambiguous, the Court need not address B+L's argument that it should be permitted additional discovery regarding "documents essential to a presentation of parol evidence." (ECF No. 47-2, at 23-24).

[22] *See* ECF No. 47-1, ¶ 7.

> [Either central cornea staining or total cornea staining] is acceptable as a "sign endpoint" when coupled with a "symptom endpoint" to support the efficacy of a product for the treatment of dry eyes. The use of proprietary testing procedures may raise questions about the ability to generalize the test results to support a more generalized label.

Meeting Minutes at 2.

B+L argues that the FDA's response to Question 1 is insufficient to render the Initial Phase III Trial Inconclusive. ECF No. 47-2, at 18-19. Specifically, B+L points out differences between the language in section 1.41(b)(2) and the language used by MPI and the FDA. Section 1.41(b)(2) involves whether the FDA agrees that a sign or a symptom can be used as the "primary sign or symptom," whereas MPI asked whether cornea staining could be used as a "primary sign endpoint" and the FDA agreed that it was acceptable as a "sign endpoint." But as discussed above, the differences between these terms are negligible. The word "primary," like the word "endpoint," is used to identify which variable (or variables) will be used to determine whether the trial meets its objectives. By giving an affirmative answer to Question 1, the FDA agreed that central cornea staining and total cornea staining could be used as that type of variable.

Similarly, the FDA stated that cornea staining could be used as a sign endpoint "when coupled with a 'symptom endpoint.'" But section 1.41(b)(2) applies when the FDA does not agree that "either a sign *or* a symptom" can be used as "the primary sign *or* symptom" to support approval. Agreement § 1.41(b)(2) (emphasis added). Given the Agreement's use of the disjunctive, the FDA did not qualify its response to Question 1 in any way that would affect whether section 1.41(b)(2) applies.[23]

[23] B+L's argument regarding the differences between section 1.41(b)(2) and the Meeting Minutes is further belied by the deposition testimony of B+L's representative Sharon Tonetta:

> Q: Now, is it your understanding that the FDA told Mimetogen that endpoints that were assessed during the initial Phase III trial could be used as primary endpoints in a subsequent trial in order to seek product approval?
> A: Correct.

Lastly, B+L argues that the FDA's answer to Question 3—rather than Question 1—should determine whether the Initial Phase III Trial was Inconclusive. In Question 3, MPI asked:

> If the following sign and symptom endpoints, specifically, change from Pre-CAE_{SM} to Post-CAE_{SM} in fluorescein staining in the central region or total cornea (sum of the inferior, central and superior regions) and one of the following OSDI questions "blurred vision" or "poor vision" that demonstrated improvements in the recently completed Phase 3 study (MIM-725) are replicated as primary endpoints in a subsequent Phase 3 study, would the clinical data from these two Phase 3 studies and the Phase 2 study (MIM-724) be sufficient evidence to support efficacy of a dry eye indication? Would an additional efficacy study be required?

Meeting Minutes at 4. The FDA responded as follows:

> A single efficacy study is unlikely to be sufficient to support a New Drug Application (NDA) because after an adjustment for multiplicity, it appears that neither of the completed studies demonstrated efficacy of the proposed drug product. It is recommended that at least two additional efficacy studies be conducted.

Id.

B+L's argument fails because Question 3 is irrelevant to this case. Question 3 is a hypothetical question about data and how many additional efficacy studies would be required to secure FDA approval. For the reasons discussed above, those concepts are beyond the scope of section 1.41(b)(2). Rather, section 1.41(b)(2) is unambiguous and concerns only whether a sign or a symptom (*i.e.*, a variable) that was assessed at the Initial Phase III Trial could be used as the primary variable (*i.e.*, endpoint) in support of FDA approval.

The FDA's affirmative answer to Question 1 means that section 1.41(b)(2) does not apply and that the Initial Phase III Trial was Inconclusive. B+L therefore breached section 5.5(c) of

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> Q: And in fact there were two sign endpoints assessed in the initial Phase III trial that the FDA indicated to Mimetogen could be used as primary sign endpoints in support of product approval in a subsequent trial, correct?
> A: There were two exploratory variables that could be used as endpoints, primary endpoints in additional studies.
> Q: The FDA told Mimetogen that that -- that those endpoints were acceptable to use as primary endpoints in subsequent studies, correct?
> A: Correct.

ECF No. 41-10, Tonetta Dep. at 83:14 - 84:13.

the Agreement by failing to pay the $20 million exit fee when it declined to exercise or extend the Option. Accordingly, MPI's motion for partial summary judgment (ECF No. 41) is GRANTED.

CONCLUSION

For the reasons stated above, the motion for summary judgment filed by B+L and Valeant (ECF No 47) is DENIED and the motion for partial summary judgment filed by MPI (ECF No. 41) is GRANTED.

IT IS SO ORDERED.

Dated: June 30, 2017
Rochester, New York

HON. FRANK P. GERACI, JR.
Chief Judge
United States District Court